IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Elizabeth King, et al.

APPLICATION NO.: 09/425,622

Examiner: J. Spear
Group Art Unit: 1615

FILING DATE: October 22, 1999

TITLE: Controlled-Release Pharmaceutical Formulations

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on this 15th day of January 2003

By

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Response To Non-Final Office Action

This is in response to the non-Final Office Action dated July 16, 2002 in the above-identified application, the term for response having been extended three (3) months by including the appropriate fee and petition herewith.

In response to the Office Action, please make the following changes to the application:

In the claims:

42. (Once Amended) A formulation as claimed in claim 41, wherein the core further comprises a buffering agent.

Cancel claims 44 and 45 without waiver or prejudice.

46. (Once Amended) A process for the production of a sustained-release formulation comprising a cGMP PDE-5 inhibitor embedded in a matrix from which it is released by diffusion or erosion, which comprises the steps of:

(a) mixing the cGMP PDE-5 inhibitor with a matrix material, and pressing into tablets;

(b) forming a core comprising the cGMP PDE-5 inhibitor and then coating the core with a release rate-controlling membrane; or

(c) forming a core containing the cGMP PDE-5 inhibitor and then coating the core with a coating impermeable to the cGMP PDE-5 inhibitor;